



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/599,943

06/29/2007

Rob Short

P-7735

6981

32752 7590 03/29/2010
David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Hoffman & Baron)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

EXAMINER

LE, EMILY M

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

03/29/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,943	SHORT ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/13/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/30/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 26-27 are added. Claims 1-27 are pending and under examination.

Claim Objections

2. Claim 7 is objected to because of the following informalities: Improper Markush language. The claim recites "or" instead of "and" between the last two Markush members. Appropriate correction is required.

Information Disclosure Statement

3. The information disclosure statement filed 1/30/2008, in part, fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Specifically, the non-patent literatures listed therein fails to comply with 37 CFR 1.98 (b)(5),

Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Short et al.¹

The claims are directed to a process for the disassociation of at least one biological entity from a plasma polymerized surface of an organic monomer comprising contacting the surface with at least one agent which promotes disassociation of said entity from said surface. Claim 2, which depends on claim 1, requires the biological entity to be a carbohydrate. Claim 3, which depends on claim 2, requires the carbohydrate to be a homopolysaccharide. Claim 4, which depends on claim 2, requires the carbohydrate to be a heteropolysaccharide. Claim 5, which depends on claim 4, requires the heteropolysaccharide to be glycosaminoglycan. Claim 6, which depends on any of claims 2-5, requires the carbohydrate to be a sulphated biomolecule. Claim 7, which depends on claim 5, requires the glycosaminoglycan to be selected from the group consisting of hyaluronan, dermatan sulfate, chondroitin sulfate, heparin, heparan sulphate and keratan sulphate. Claim 8, which depends on claim 1, requires the biological entity to be a polypeptide. Claim

¹ Short et al. WO 2004/040308 A1, published May 13, 2004.

Art Unit: 1648

9, which depends on claim 1, requires the biological entity to be a nucleic acid molecule. Claim 10, which depends on claim 1, requires the nucleic acid molecule be selected from the group consisting of DNA, RNA and peptide oligonucleotides. Claim 11, which depends on claim 1, requires the biological entity to be a cell or viral particle. Claim 12, which depends on claim 1, requires the surface to comprise a plasma polymer of a volatile acid. Claim 13, which depends on claim 12, requires the surface to comprise at least 5% of said volatile acid. Claim 14, which depends on claim 1, requires the surface to comprise a plasma polymer of a volatile alcohol. Claim 015, which depends on claim 1, requires the surface to comprise a plasma polymer of a volatile amine. Claim 16, which depends on claim 1, requires the surface to comprise a mixture of volatile acid and volatile hydrocarbon. Claim 17, which is directed to the method of claim 1, with the exception that the instant method requires the contacting active step to be repeated to remove additional biological entity from the plasma polymer surface. Claims 18-26, which depend on claims 17, 18, 18, 20, 21, 17, 17, 17 and 6, respectively, recite the limitation of claims 2-5, 7-9, 11 and 7, respectively. Claim 27, which depends on claim 10, requires the DNA to be selected from cDNA, genomic DNA, single stranded DNA and oligonucleotides.

Prior to the rejection, it is noted that the instant specification discloses the following:

"Agent" is defined as any means that results in the disassociation of molecules bound to the product of the invention. The interaction of carbohydrate with the plasma polymerized surface is an ionic interaction and therefore it will be apparent that any means that results in disruption of ionic bonding will release at least the biological entity from the plasma polymer surface. Examples include, but are not limited to, alteration in the ionic strength, modulation of pH,

Art Unit: 1648

the use of detergents and solvents. It will also be apparent that an "agent" may be an environmental agent, for example alteration of temperature. Combinations of agent may also be used in the method of the invention. Conditions may also be determined that allow the removal of just a biological molecule bound to a protein, nucleic acid or carbohydrate molecule. [Lines 11-20, page 5.]

Short et al. teaches a process for the association of at least one biological entity from a plasma polymerized surface of an organic monomer comprising contacting the surface with at least one agent which promotes association of said entity from said surface. [Abstract, entire reference.] The biological entity Short et al. teaches is carbohydrates, including homopolysaccharide and heteropolysaccharide. The heteropolysaccharide that Short et al. teaches are hyaluronan, dermatan sulfate, chondroitin sulfate, heparin, heparan sulphate and keratan sulphate, all of which are glycosaminoglycan and some are sulfated molecules. Short et al. also teaches polypeptides, genomic DNA, and cells as the biological entity. Short et al. teaches the surface comprises volatile acid, volatile alcohol and mixtures thereof.

Short et al. does not teach the disassociation of the biological entity from plasma polymerized surface of an organic monomer. However, Short et al. discloses that the interaction between the biological entity and the plasma polymerized surface of an organic monomer is non-covalent, electrostatic, hydrophilic or hydrophobic--ionic. Thus, to facilitate association between the biological entity and the plasma polymerized surface of an organic monomer, Short et al. suggests varying the pH, the negative charge of the carbohydrate, the positive charge of the plasma polymerized surface of an organic monomer, the use of phosphate buffered saline or

Art Unit: 1648

a solution of physiologically ionic strength. Thus, at the time the invention was made, Short et al. establishes that these agents effect the association between the biological entity with the plasma polymerized surface of an organic monomer.

Hence, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to vary these very same to influence association/disassociation. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to facilitate disassociation of the biological entity to the plasma polymerized surface of an organic monomer. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the determination of a workable or optimal working condition is routinely practiced in the art.

Regarding claim 13, which depends on claim 12, requires the surface to comprise at least 5% of said volatile acid. It is not readily apparent the % of the volatile acid present on the plasma polymerized surface of an organic monomer, wherein the volatile acid is the organic monomer. However, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to use varying % of the organic monomer. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to optimize the binding surface. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the determination of a workable or optimal working condition is routinely practiced in the art.

Art Unit: 1648

Regarding claim 17, which requires the contacting active step to be repeated to remove additional biological entity from the plasma polymer surface. In the instant case, it would have been prima facie obvious for one of ordinary skill in the art to repeat the contacting active step. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to optimize the disassociation of the biological molecule from the plasma polymerized surface of an organic monomer. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the determination of a workable or optimal working condition is routinely practiced in the art.

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./
Primary Examiner, Art Unit 1648